

FEB 02 2007

Atty Dkt. No.: PALO-004  
USSN: 10/748,976**REMARKS**

In view of the following remarks, the Examiner is requested to allow Claims 1-11 and 17-20, the only claims pending and under examination in this application.

***Claim Rejections - 35 U.S.C. § 103***

Claims 1, 4, 7, 9, 10, 17, 18 and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,522,854).

According to the M.P.E.P. § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The rejected claims are directed to a method of treating a female subject for a fertility condition. The method includes modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat the female subject for the fertility condition. The method further includes determining the sympathetic activity/parasympathetic activity ratio prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.

Accordingly, elements of the rejected claims are determining a sympathetic activity/parasympathetic activity ratio and modulating a portion of the autonomic

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nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition.

The Office asserts that Rezai discloses a device for modulating a portion of the autonomic nervous system of a female subject wherein the device is capable of treating a fertility condition. The Office acknowledges that Rezai is deficient in that it fails to teach determining a sympathetic activity/parasympathetic activity ratio and modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. The Office, therefore, relies upon Ideker to remedy the deficiencies of Rezai.

The Applicants, however, respectfully disagree and contend that a *prima facie* case of obviousness has not been established because there is no motivation to combine the references in the manner suggested. Specifically, there is no motivation to combine the references so as to treat a female subject for a fertility condition.

As described in the Applicants' previous response, Rezai discloses affecting a "hypothalamic-related condition" by electrically or chemically stimulating the hypothalamus (see Abstract). Rezai discloses a list of over 55 conditions allegedly related to the hypothalamus. These conditions include an extremely diverse range of conditions including arrhythmia, baldness, narcolepsy, lethargy, dwarfism, facial blushing, as well as infertility (page 3, Table II). However, Rezai does not provide any teaching or suggestion as to how the method is to be applied specifically to each condition.

Ideker, on the other hand, is directed to a method for preventing arrhythmia by nerve stimulation. To the extent that Ideker discloses monitoring the ratio of sympathetic nerve activity to parasympathetic nerve activity it is for the purpose of detecting a high risk of arrhythmia. See column 1, lines 53 to 56. Further, in measuring the ratio of sympathetic to parasympathetic nerve activity, Ideker discloses that it is a

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subject's heart rate variability that is measured. See column 3, lines 49 to 52. Additionally, to the extent that Ideker discloses stimulating a nerve it is an afferent nerve to the heart. See column 2, lines 60 to 62. Hence, at most Ideker suggest monitoring a ratio of sympathetic nerve activity to parasympathetic nerve activity so as to detect a high risk of arrhythmia.

Therefore, based on Ideker's disclosure of determining a high risk of heart arrhythmia, there is no suggestion to modify Rezai in view of Ideker so as to treat a female subject for a fertility condition. At most, if one were to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia. Hence, there is no motivation to combine the references in the manner suggested because Ideker is directed to treating arrhythmia, not a female fertility condition.

In view of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because there is no motivation to combine Rezai with Ideker in the manner suggested. There is no motivation to combine Rezai with Ideker in the manner suggested because Ideker is directed to preventing arrhythmia and at most if one of skill in the art were motivated to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia and not a female fertility condition. Consequently, the Applicants respectfully request that the Office reconsider and withdraw the 35 U.S.C. § 103(a) rejection of Claims 1, 4, 7, 9, 10, 17, 18 and 20.

Claims 2 and 3 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, or in the alternative over Rezai in view of Ideker and further in view of Bothe Loncar et al. (US Publication No. 2002/0188336).

Claims 2 and 3 depend from Claim 1. As set forth above, elements of the rejected claims determining a sympathetic activity/parasympathetic activity ratio and modulating a portion of the autonomic nervous system based on the determined

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sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. As described above, Rezai cannot be combined with Ideker in the manner suggested because there is no motivation to combine Rezai with Ideker in the manner suggested. There is no motivation to combine Rezai with Ideker in the manner suggested because Ideker is directed to preventing arrhythmia and at most if one of skill in the art were motivated to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia and not a female fertility condition, which is not what the Applicants are claiming. As Bothe Loncar is cited solely for its alleged disclosure of modulating the autonomic nervous system during the luteal phase of the menstrual cycle, it fails to remedy the deficiencies of Rezai in view of Ideker. Therefore, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 2 and 3 be withdrawn.

Claims 5, 6 and 11 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to claims 1-9 above, and further in view of Whitehurst et al. (USPN 6,832,114).

Claims 5, 6 and 11 depend from Claim 1. As set forth above, elements of the rejected claims determining a sympathetic activity/parasympathetic activity ratio and modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. As described above, Rezai cannot be combined with Ideker in the manner suggested because there is no motivation to combine Rezai with Ideker in the manner suggested. There is no motivation to combine Rezai with Ideker in the manner suggested because Ideker is directed to preventing arrhythmia and at most if one of skill in the art were motivated to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia and not a female fertility condition, which is not what the Applicants are claiming. As Whitehurst is cited solely for its alleged disclosure of inhibiting parasympathetic stimulation or activating sympathetic stimulation so as to modulate the nerves of an organ (i.e., the pancreas so as to treat diabetes), it fails to remedy the

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deficiencies of Rezai in view of Ideker. Therefore, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 5, 6 and 11 be withdrawn.

Claim 8 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to Claim 7 above, and further in view of Mann et al. (US Publication No. 2002/0055761).

Claim 8 depends from Claim 1. As set forth above, elements of the rejected claims determining a sympathetic activity/parasympathetic activity ratio and modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. As described above, Rezai cannot be combined with Ideker in the manner suggested because there is no motivation to combine Rezai with Ideker in the manner suggested. There is no motivation to combine Rezai with Ideker in the manner suggested because Ideker is directed to preventing arrhythmia and at most if one of skill in the art were motivated to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia and not a female fertility condition, which is not what the Applicants are claiming. As Mann is cited solely for its alleged disclosure of stimulating a pelvic nerve (i.e., to reduce or eliminate a bladder problem), it fails to remedy the deficiencies of Rezai in view of Ideker. Therefore, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 8 be withdrawn.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to Claim 1 above, and further in view of Khan et al. (US Publication No. 2002/0064501).

Claim 19 depends from Claim 1. As set forth above, elements of the rejected claims determining a sympathetic activity/parasympathetic activity ratio and modulating

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a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. As described above, Rezai cannot be combined with Ideker in the manner suggested because there is no motivation to combine Rezai with Ideker in the manner suggested. There is no motivation to combine Rezai with Ideker in the manner suggested because Ideker is directed to preventing arrhythmia and at most if one of skill in the art were motivated to modify Rezai in view of Ideker it would be for the purpose of treating arrhythmia and not a female fertility condition, which is not what the Applicants are claiming.

The addition of Khan does not remedy the deficiency of Rezai and Idekar. Khan discloses using an immunoregulator to treat an immune-mediated disorder, including "chronic inflammatory disease, such as diabetes type I or II, rheumatic disease, Sjogrens syndrome, multiple sclerosis, transplantation-related immune responses such as graft-versus-host-disease, post-transfusion thrombocytopenia, chronic transplant rejection, pre-eclampsia, atherosclerosis, asthma, allergy and chronic auto-immune disease, and acute inflammatory disease" (paragraph [0028]). However, Khan does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio. Therefore, Khan does not remedy the deficiencies of Rezai and Idekar. Consequently, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 19 be withdrawn.

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CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALO-004.

Respectfully submitted,  
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Date: February 2, 2007

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